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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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IRVINE, CA 92618				
			ART UNIT	PAPER NUMBER
			1615	
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			09/24/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/598,396	HOFFMANN, ERIKA	
	Examiner	Art Unit	
	DENNIS HEYER	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-36,38-41,45-48,58-60 and 71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 32-36,38-41,45-48,58-60 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement is made of Applicant's remarks and amendments filed August 11, 2009. Acknowledgement is made of the cancellation of Claims 37, 42 – 44, 49, 56, 57 and 65 – 70 and the addition of Claim 71 in the response filed August 11, 2009. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Status of Claims

Claims 32 – 36, 38 – 41, 45 – 48, 58 – 60 and 71 are currently pending.

Withdrawn Objections

Abstract Objection

The Objection to the Abstract for use of improper language and format for an abstract is rendered moot and is withdrawn in response to Applicant's amendments.

Withdrawn Rejections

Claim rejections – 35 USC § 112 – 2nd Paragraph

The rejection of Claims 40 and 45 as lacking antecedent basis is rendered moot and is withdrawn in response to Applicant's amendments. The rejection of Claims 56 - 60 and 65 - 70 as incomplete and unclear in scope for being dependent from cancelled claims is rendered moot and is withdrawn in response to Applicant's amendments.

Claim rejections – 35 USC § 102

The rejection of Claims 32 – 36, 38 – 39, 45 – 47 as being anticipated by Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 as evidenced by Mallegol *et al.* in Progress in Organic Coatings, 39 (2000), 107 – 113 under 35 U.S.C. 102(b) is rendered moot and is withdrawn in response to Applicant's amendments.

Accordingly, in view of the amended Claims a new ground of rejection is presented below which meets the limitations recited in Claim 32.

Claim rejections – 35 USC § 103

The rejection of Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 as evidenced by Mallegol *et al.* in Progress in Organic Coatings, 39 (2000), 107 – 113, in view of Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 is rendered moot and is withdrawn in response to Applicant's amendments.

Accordingly, in view of the amended Claims a new ground of rejection is presented below which meets the limitations recited in Claim 32.

New Rejections

Claim rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Instant Claims 32 – 36, 38 – 39, 45 – 47, 58 – 60 and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 as evidenced by Russell in Tung and Linseed Oils, web.archive.org/web/20031204011520/http://www.sydneywoodturners.com.au/site/articles/finishing/oils.html.

Regarding instant Claims 32 – 36, 38 – 39, the Allen-Petit reference teaches medical products (Abstract, “intraluminal prosthesis, shunt, catheter or local drug delivery device”) comprising Applicant elected specie (a) Linseed oil, as the substance that participates in the polymerization (Claim 11, “a device characterized in that said oil or fat comprises an either or not chemically modified”, “in particular fish oil, sunflower oil, linseed oil”). Regarding the weight limitation of the substance, linseed oil that participates in the polymerization reaction (Claims 32 and 39); the reference teaches a device in which the fat or oil coating comprises at least 70 % by weight (Claim 12).

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It is noted that the reference does not explicitly teach that linseed oil 'polymerizes', however, the method taught by Allen-Petit in applying the disclosed fats and oils to a stent (including linseed oil) (pages 9, lines 18 - 29 and page 10, lines 1 - 9), which include air drying the prosthesis following applying the oil/solvent emulsion, optionally, more than once, would necessarily result in at least a partial polymerization of linseed oil. Russell, who is cited herein as an evidentiary reference, teaches that the drying of linseed oil is a result of polymerization by the action of atmospheric oxygen (autoxidation) (page 1, 3rd paragraph). Thus, the method taught by Allen-Petit exploits a naturally occurring property of linseed oil, resulting in a product necessarily comprising, at least partially, a linseed oil-derived polymer coated medical product.

Regarding the newly added limitation that the polymerization takes place by exposure to aerial oxygen and UV after coating the surface of the medical product, it is noted that this is a product-by-process limitation and the patentability of product-by-process claims is based on the product itself. It has been held that whether the rejection is based on inherency' under 35 U.S.C. 102, on *prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. In re Fitzgerald, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)).

Thus the burden is shifted to Applicant to provide evidence that the linseed oil polymer obtained by the limitations recited in instant Claim 32, a medical product the

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surface of which comprises, at least partially, a linseed oil polymer layer, and that obtained by the prior art product of Allen-Pettit are distinct.

Regarding instant Claims 45 – 47, in which the medical device of instant Claim 32 comprises a substance that does not participate in the polymerization. It is noted that these Claims have been amended to depend from newly added Claim 71.

As noted above, the Allen-Petit reference teaches a medical device that anticipated the limitations of instant Claims 32 – 36, 38 – 39. The reference also teaches the limitations of instant Claims 45 – 46, in which said medical device further comprises Applicant-elected specie (c) paclitaxel (Claim 21, page 6, line 5 – 7).

Regarding the limitation of instant Claim 47, the reference teaches that the therapeutic agent, paclitaxel, may be bound adhesively in the polymer layer (page 2, lines 9 – 11. “the matrix which comprises the therapeutic agent is formed by the biocompatible oil or fat”).

With regard to Claims 58 – 60, it is noted that these Claims have now been amended to depend from instant Claim 32 instead of cancelled Claim 1. Allen-Petit teaches the medical device is a stent (Abstract) and that a therapeutic agent is selected having anti-antirestenotic action (page 6, lines 5 – 23). Thus the medical device of Allen-Petit is suitable to prevent or reduce restenosis.

Regarding instant Claim 60, Allen-Petit teaches a coating that is bio-compatible and enabled for sustained (continuous) release of therapeutic agent. Thus the, medical product of Allen-Petit is suitable to continuous release of active agents including Applicant-elected paclitaxel.

Regarding instant Claim 71, Allen-Petit teaches substances, such as a therapeutic agent, that do not participate in the polymerization (drying) reaction (Abstract).

Claim rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 48 is rejected under 35 U.S.C.103(a) as being unpatentable over Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003 as evidenced by Russell in Tung and Linseed Oils, web.archive.org/web/20031204011520/http://www.sydneywoodturners.com.au/site/articles/finishing/oils.html, as applied to Claims 32 – 36, 38 – 39, 45 – 47, 58 – 60 and 71 in the 102(b) rejection

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above, in view of Allen-Petit *et al.* in WO 2003/039612, publication date: May 15, 2003.

.As noted in the 102(b) rejection above, the Allen-Petit reference teaches a medical device comprising Applicant elected species a) and c), linseed oil and paclitaxel, respectively that anticipated the limitations of instant Claims 32 – 36, 38 – 39 and 45 – 47.

Regarding instant Claim 48, drawn to the concentration of active agent on the surface of the medical product, Allen-Petit teaches a medical device comprising Applicant elected species a), linseed oil, and a therapeutic agent. As noted in the 102(b) rejection of instant Claims 45 – 47, the therapeutic agent may be paclitaxel, however Allen-Petit does not teach a concentration of paclitaxel on the surface of the medical device. Allen-Petit does teach a pharmaceutically active concentration of the therapeutic agent tacrolimus of 800 μg deposited onto a 4.8 cm^2 eicosapentaenoic acid coated stent (page 20, line 20). This provides a concentration of active agent equal to 0.16 mg/cm^2 , (within the range cited in instant Claim 48). The limitation that the concentration taught by Allen-Petit be pharmaceutically active was demonstrated by a >20% reduction in in-stent neointimal hyperplasia (page 20, lines 23 – 29). Thus it would have been *prima facie* obvious, to one of ordinary skill in the art, at the time the invention was made, to use the concentration provided by the teachings of Allen-Petit when substituting one therapeutic agent (tacrolimus) for another (paclitaxel).

Claims 40 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen-Petit *et al.* in WO 2003/039612, as evidenced by as evidenced by Russell

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in Tung and Linseed Oils, web.archive.org/web/20031204011520/

<http://www.sydneywoodturners.com.au/site/articles/finishing/oils.html>, as applied to Claims 32 – 36, 38 – 39, 45 – 47, 58 – 60 and 71 in the 102(b) rejection above, and further in view of Kashiwagi *et al.* in US patent 5,336,698; published: August 9, 1994.

The Allen-Petit reference, as noted in the 102(b) rejection above, teaches a medical device comprising Applicant elected species (a) and (c), linseed oil and paclitaxel, respectively that anticipated the limitations of instant Claims 32 – 34, 38 – 39 and 46 – 47. The Allen-Petit reference also teaches the pharmaceutically active concentration range cited in instant Claim 48 for an active agent (103 rejection above).

Instant Claims 40 and 41, drawn to substances not participating in the polymerization reaction, have been amended to depend from newly added Claim 71. Regarding instant Claims 40 and 41, Allen-Petit teaches that the oils or fats may also contain free fatty acids (page 5, lines 10 – 18) but does not teach Applicant -elected specie palmitinic acid. It is noted that palmitinic acid is commonly referred to as palmitic acid and that the latter name will be used forthwith as it is the name used in the cited prior art references.

Kashiwagi teaches incorporation of palmitic acid as a ligand for a medical material and notes the superior blood compatibility of fatty acids, including the saturated fatty acid palmitic acid (column 2, lines 45 – 57). Kashiwagi also teaches that bonding of a fatty acid to a medical material may reduce or prevent undesirable physiological properties such as blood clotting, activation of the complement system and platelet

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adhesion (Abstract). Thus the motivation to combine palmitic acid with the medical product of instant Claim 71 is provided by Kashiwagi. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made, to incorporate the guidance from the teachings of Kashiwagi and add palmitic acid, a known blood biocompatible fatty acid, to a medical product designed to be in intimate contact with blood vessels for the purpose of reducing undesired physiological properties.

Response to Arguments

As noted above, Applicant's arguments with respect to the rejections under 102(b) and 103(a) have been fully considered but are moot in light of the Claim amendments which necessitated the new ground of rejection presented above.

The Examiner will now address any outstanding issues relevant to the Allen-Petit reference raised in Applicant's response filed August 11, 2009. Applicant argues extensively on pages 15 – 18 of the response against the Examiner's 102(b) rejection that the teachings of Allen-Petit exploited a naturally occurring property of linseed oil, specifically air-catalyzed polymerization (autopolymerization). Applicant has amended the claims to require a polymerization process in which the linseed oil is coated onto a medical device and then exposed to air and UV radiation. Applicant's amendment has added a product-by-process limitation to instant Claim 32 which has been rejected in the currently applied 102(b) rejection. Applicant argues that polymerization would be "impossible" under the conditions cited by Allen-Petit but has failed to provide any

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evidence for this assertion. Applicant notes that in the evidentiary reference currently applied by Russell, clearly states that the drying of linseed oil is a result of polymerization by the action of atmospheric oxygen (autoxidation). The precise mechanism or, whether the drying (polymerization) is aggressive (page 15, 6th paragraph of response), whether the polymerization goes to completion (page 16, 6th paragraph) or, whether the conditions by Allen-Petit are commercially viable (page 18, 2nd paragraph) are not relevant to the claim limitations. The burden on Applicant as noted in the 102(b) rejection above is to provide objective evidence that the instantly claimed product, a medical product the surface of which comprises, at least partially, a linseed oil polymer layer, is distinct from the prior art of Allen-Petit.

Conclusion

Claims 32 – 36, 38 – 41, 45 – 48, 58 – 60 and 71 are rejected. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DENNIS HEYER whose telephone number is (571)270-7677. The examiner can normally be reached on Monday-Thursday 8AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, MICHAEL WOODWARD can be reached at (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DH

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615